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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,284	08/15/2000	Takumi Sasaki	20-4736P	9843

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EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 07/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/622,284	SASAKI ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-7 and 9-13* is/are pending in the application.

4a) Of the above claim(s) *6 and 7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5 and 9-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 04/05/04 in response to the non-final Office Action mailed 10/06/03. With this, Applicants amended the specification.

Status of Claims

2) Claims 2, 4 and 8 have been canceled via the amendment filed 04/05/04 .

Claims 1, 3, 5 and 9-13 have been amended via the amendment filed 04/05/04 .

Claims 1, 3, 5-7 and 9-13 are pending.

Elected claims 1, 3, 5 and 9-13 are under examination.

Prior Citation of Title 35 Sections

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

5) The objection to the abstract made in paragraph 8 of the Office Action mailed 10/06/03 is withdrawn in light of Applicants' amendment to the abstract.

6) The objection to the specification made in paragraph 9(c) of the Office Action mailed 04/23/03 and maintained in paragraph 10 of the Office Action mailed 10/14/03 is withdrawn in light of MPEP 608.01 and Applicants' argument.

Rejection(s) Moot

7) The rejection of claims 2, 4 and 8 made in paragraph 10 of the Office Action mailed 10/06/03 under 35 U.S.C. § 112, first paragraph, as containing inadequate written description, is moot in light of Applicants' cancellation of the claims.

8) The rejection of claim 2 made in paragraph 13(c) of the Office Action mailed 10/06/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

9) The rejection of claim 4 made in paragraph 13(d) of the Office Action mailed 10/06/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

10) The rejection of claim 8 made in paragraph 13(e) of the Office Action mailed 10/06/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

11) The rejection of claims 2, 4 and 8 made in paragraph 13(f) of the Office Action mailed 10/06/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

12) The rejection of claims 2, 4 and 8 made in paragraph 13(I) of the Office Action mailed 10/06/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

13) The rejection of claims 2, 4 and 8 made in paragraph 13(k) of the Office Action mailed 10/06/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

14) The rejection of claims 1, 3, 5 and 9-13 made in paragraph 10 of the Office Action mailed 10/06/03 under 35 U.S.C. § 112, first paragraph, as containing inadequate written description, is withdrawn. A modified rejection is made below to meet the claims, as amended.

15) The rejection of claim 1 made in paragraph 13(a) of the Office Action mailed 10/06/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

16) The rejection of claim 1 made in paragraph 13(b) of the Office Action mailed 10/06/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

17) The rejection of claim 3 made in paragraph 13(c) of the Office Action mailed 10/06/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

18) The rejection of claim 5 made in paragraph 13(d) of the Office Action mailed 10/06/03 under

35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

19) The rejection of claim 9 made in paragraph 13(e) of the Office Action mailed 10/06/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

20) The rejection of claims 1, 3, 5 and 9 made in paragraph 13(f) of the Office Action mailed 10/06/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn. A modified rejection is made below to meet the claims, as amended.

21) The rejection of claim 1 made in paragraph 13(g) of the Office Action mailed 10/06/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn. A modified rejection is made below to meet the claims, as amended.

22) The rejection of claim 1 made in paragraph 13(h) of the Office Action mailed 10/06/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

23) The rejection of claims 3, 5 and 9 made in paragraph 13(I) of the Office Action mailed 10/06/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

24) The rejection of claim 13 made in paragraph 13(j) of the Office Action mailed 10/06/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

25) The rejection of claims 2, 5 and 9-13 made in paragraph 13(k) of the Office Action mailed 10/06/03 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s).

26) The rejection of claims 1 and 13 made in paragraph 15 of the Office Action mailed 10/06/03 under 35 U.S.C. § 102(b) as being anticipated by the Canadian patent 2,084,120A1 (31 May 1994) or Bill Jerome *et al.* (WO 96/40235), is withdrawn in light of Applicants' amendment to the claims or the base claim.

27) The rejection of claims 1, 3, 5 and 9-13 made in paragraph 16 of the Office Action mailed 10/06/03 under 35 U.S.C. § 102(b) as being anticipated by Kappler *et al.* (WO 93/14634 -

Applicants' IDS), is withdrawn. A modified rejection is made below to meet the claims, as amended.

New Rejection(s)

Applicants are asked to note the following new rejection(s) made in this Office. The new rejections are necessitated by Applicants' amendments to the claim(s).

Rejection(s) under 35 U.S.C. § 112, First Paragraph

28) Claims 1, 3, 5 and 9-13 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The recitation 'derivatives thereof' in the instant claims, as amended, is interpreted as encompassing derivatives of SEB having substitution at 9, 23 or 44 position. It is noted that the 'derivatives' recited in the instant claims do not exist independent of their function(s), i.e., inhibitory activity on T cell activation, interaction with specific Vβ component of T cell receptor (TCR), reduced immunological responsiveness, and prophylactic activity against immunopathy, including rheumatoid arthritis. The specification discloses prophylactic or therapeutic applications or intentions for the claimed 'derivatives'. However, the instant specification fails to teach a single 'derivative' of 9-substituted, 23-substituted and/or 44-substituted SEB having the above-cited functional activities. Prophylactic or therapeutic applications minimally require a specific inhibitory action of derivatives on T cell activation and reduced immunological responsiveness. The precise structure or relevant identifying characteristics of each 'derivative' of substituted SEBs as recited having the above-cited functional activities can only be determined empirically by actually making every DNA molecule that encodes the 'derivative', and testing each DNA molecule to determine whether it encodes the 'derivative' having the particularly disclosed biological activities. The *Written Description Guidelines* state:

> There is an inverse correlation between the level of predictability in the art and the amount of disclosure necessary to satisfy the written description requirement. For example, if there is a well-established correlation between the structure and function in the art, one skilled in the art will be able to reasonably predict the complete structure of the claimed invention from its function.

A mere statement in the specification that the invention includes the use of such a 'derivative' as a prophylactic or remedy for immunopathy is insufficient to meet the adequate written description

requirement of the claimed invention. The SEB molecule has specific functional or biologic properties dictated by the structure of the toxin and the corresponding structure of the gene sequence which encodes it. A convincing structure-function relationship has to exist between the structure of the gene sequence, the structure of the toxin derivative encoded, and the function of the encoded toxin derivative. The function cannot be predicted from the modification of the structure of the gene and in the instant case, the DNA encoding the 'derivative' of the substituted SEB. Applicants have not shown that derivatization of a reference gene sequence encoding a reference substituted SEB as claimed would automatically predict the production of a 9-substituted, 23-substituted and/or 44-substituted SEB 'derivative' having the recited functional activities. The specification fails to teach the structure or relevant identifying characteristics of a representative number of species of DNA molecules encoding a representative number of species of 'derivatives' of substituted SEB as recited, sufficient to allow one skilled in the art to determine that the inventors had possession of the invention as claimed. With the exception of a modified SEB having specific amino acid substitutions, for example, at position 9, 23 or 44 of a native staphylococcal SEB, a skilled artisan cannot envision the detailed chemical structure of all the 'derivative' species encompassed by the recited molecule. Regardless of the complexity or simplicity of the method of isolation, conception cannot be achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that its is a part of the invention and a reference to a potential method of isolating it. The 'derivatives' of the specifically substituted SEB, or the DNAs encoding the 'derivatives' themselves are required. See *Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993)* and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.*

29) Claims 1, 3, 5 and 9-13 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1, 3, 5 and 9, as amended, include the limitations: 'at a position corresponding to the ....-position of natural type SEB'. Applicants state that the support for the amended subject matter comes from originally filed claims 2, 4 and 8. However, there appears to be no descriptive support for the above-identified limitations in these originally filed claims. Therefore, the above-identified

new limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the newly added limitations, or to remove the new matter from the claims.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

30) Claims 1, 3, 5 and 9-13 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 1, 5 and 9 are vague and indefinite in the recitation: 'derivative thereof', because it is unclear what is encompassed in this recitation. What constitutes a derivative, and how much of the substituted SEB's original structure has to be retained such that the resulting product can be considered as a 'derivative thereof', is not clear. The metes and bounds of the structure encompassed in the limitation 'derivative' is indeterminate.

(b) Claim 13 improperly depends from a canceled claim.

(c) Claim 1 is vague, indefinite and confusing in the recitations: 'natural type SEB', 'SEB' [see line 10 and the beginning of parts (a), (b) and (c)] and 'recombinant wild-type SEB'. It is unclear how the three SEBs differ from one another structure-wise, function-wise or scope-wise.

(d) Claims 1, 3, 5 and 9 lack antecedent basis in the limitation: 'natural type SEB' (see parts a, b and c; last line of claim 3; and line 5 of claims 5 and 9). Since the claims include an earlier recitation of 'natural type SEB', for proper antecedence, it is suggested that Applicants replace the limitation with --the natural type SEB--.

(e) Claims 3, 5 and 9-13, which depend directly or indirectly from claim 1, also stand rejected under 35 U.S.C § 112, second paragraph, because of the vagueness or indefiniteness identified above in the base claim.

Response to Applicants' Arguments on Kappler's Disclosure

31) Applicants contend that the present invention is based on the finding that SEB is efficacious for prophylaxis/remedy of immunopathy, such as, autoimmune disease. Applicants point to

Examples 6 and 7 of the specification and assert that the invention for the first time proves the therapeutic effects of the SEB modifications on the prophylaxis/remedy through oral administration in a mouse collagen-induced arthritis model.

With regard to the disclosure of Kappler *et al.* (WO 93/14634), Applicants contend that Kappler's teachings relate to: a) preparing modifications or mutations or derivatives of SEB with reduced toxicity as a representative of a superantigen from the viewpoint of its structure; and b) prophylaxis and remedy for diseases induced by toxicity of superantigen by an antibody elicited by administration of said modifications or mutations/derivatives of SEB as an antigen. Applicants submit that Kappler's teachings differ from the present invention in the diseases to which modifications, mutations or derivatives are to be administered, and in the action and mechanism thereof. Applicants state that Kappler *et al.* disclose preparing modifications or mutations/ derivatives of SEB for reducing toxicity of SEB when administered into the living body, but fail to disclose or suggest that such modifications or mutations/derivatives of SEB with reduced toxicity could be used, with high safety, for prophylaxis/remedy of autoimmune diseases, such as, rheumatoid arthritis, ulcerative colitis etc. Applicants opine that Kappler's description on pages 12-14 and 17 merely collectively disclose the knowledge at the time of filing of that application. Applicants further submit that Examples 6 and 7 of the instant specification show that the SEB modifications or derivatives thereof of the instant invention are efficacious via oral administration. Applicants assert that orally administered SEB modifications/derivatives have never hitherto been disclosed nor suggested in the prior art for the fear that SEB might be a cause of diseases such as food poisoning.

Applicants' arguments have been carefully considered, but are non-persuasive. Instant claims are not drawn to a method of treating an autoimmune disease, such as, rheumatoid arthritis, by oral administration of the modified SEBs of the instant invention. The instant claims are product claims drawn to SEBs modified at specific positions. Kappler *et al.* taught the modified SEBs that are structurally identical to the instantly claimed modified SEBs or derivatives thereof as prophylactic or therapeutic products. Although Kappler *et al.* do not expressly recite all the functional properties of their modified SEBs, including, inhibitory activity on T cell activation; interaction with specific Vβ component of T cell receptor; and reduced immunological responsiveness, these functional limitations represent the inherent properties of Kappler's modified SEBs. Because of the identical

structure and the identical bacterial origin of the prior art prophylactic or therapeutic modified SEBs, the prior art modified SEBs are viewed as the same as the modified SEBs or derivatives thereof claimed in the instant claims, and therefore these modified SEBs are expected to have the same intrinsic functional properties as that of the Applicants' modified SEBs or derivatives. The Office's position that the prior art modified SEBs are the same as Applicants' modified SEBs or derivatives thereof, is based upon the fact that every characteristic overlapping in the prior art modified SEBs and the Applicants' disclosure are the same. In spite of the fact that the prior art is silent about all of the disclosed functional characteristics of the Applicants' modified SEBs or derivatives thereof, there is sufficient overlap to reasonably conclude that the prior art modified SEBs are one and the same as the Applicants' SEBs or derivatives thereof. Since the prior art modified SEBs are structurally the same as the SEBs or derivatives thereof claimed in the instant claims, the prior art SEBs are expected to have the prophylactic capacities or properties recited in the instant claims. The functional properties are intrinsic functions inseparable from the modified SEBs of the prior art.

The recitations such as 'for immunopathy' and 'for oral administration' represent the intended use of the claimed product. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey, 152 USPQ 235 (CCPA 1967)* and *In re Otto, 136 USPQ 458, 459 (CCPA 1963)*. The recitation "for immunopathy" is not given any patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976)* and *Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951)*.

Rejection(s) under 35 U.S.C. § 102

32) Claims 1, 3, 5 and 9-13 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kappler *et al.* (WO 93/14634 - already of record).

The recitation 'SEB ..... other than aspartic acid, or a derivative thereof' in claims 1(a) and 2 is interpreted in this rejection as being directed to SEB having at least one amino acid residue corresponding to the position 9 within the amino acid sequence of natural type SEB, substituted with aspartic acid or an amino acid other than aspartic acid. Whereas the phrase 'other than aspartic acid' excludes aspartic acid substitution at position 9, the term 'derivative thereof' does not. The term 'derivative thereof' is broadly interpreted as including substitution with any amino acid including aspartic acid. Analogous interpretations apply to claims 1(b) and 5 as well as claims 1(c) and 9.

Kappler *et al.* disclosed purified modified superantigens, i.e., staphylococcal enterotoxin B (SEB) mutants, for use as a prophylactic or therapeutic product, and vaccines comprising the same, wherein the mutant superantigens interact with specific Vβ elements of T cell receptors (TCR) and elicit immune response without inducing T cell proliferation. See abstract; claims; and page 16, lines 25-29. Kappler's SEB mutants, BC-6, BC-66 and BC-88, carried isoleucine, tyrosine and lysine residues respectively at position 23 of SEB, whereas the mutant BR-291 carried serine at position 23 of SEB (see Tables II and III; and page 27). While Kappler's SEB mutants, BR-267 and BA-50, carried serine at position 44 of SEB, the mutant BA-53 carried leucine at position 43 of SEB (see Tables II and III). Kappler *et al.* also disclosed a SEB mutant, BR-257, which carried asparagine in place of aspartic acid at position 9 of SEB (see Figure 3 and last paragraph on page 27). Kappler's SEB mutants were protective when administered to monkeys and mice. The SEB mutants were ineffective or less effective in inducing an emetic response in monkeys compared to wild-type SEB (see pages 35 and 38; and Example 8). Mice and primates receiving the SEB mutant, BR-257, were fully protected from the toxic effects of SEB (see page 21). Kappler *et al.* taught of the causation of autoimmune diseases, such as, rheumatoid arthritis by natural superantigens and amelioration of such diseases in patients by partial elimination or inhibition of T cells bearing Vβ components (see paragraph bridging pages 6 and 7 as well as pages 7 and 8; first full paragraph on page 7; and second full paragraph on page 10). Kappler *et al.* taught that the amino acid residue 23N is an important amino acid for Vβ interaction and that 44F is important in binding of the SEB to class II MHC (see page 32, lines 25 and 26; page 31, lines 28, 29, 32 and 33; page 30, first paragraph; and page 20, last paragraph). The prior art vaccine formulation meant for active immunological prophylaxis and administration may contain adjuvants, carriers, or other materials (see page 16, lines 25-29; and last

two paragraphs on page 18). The mode of administration may include all of the standard methods of administering therapeutic agents to a subject (see first paragraph on page 19) and therefore includes oral administration. That the prior art SEB mutants were administered *in vivo* to mice and monkeys (see page 21) indicates that the mutants were contained in a solution of physiologically acceptable tonicity. The purified mutant SEB was contained in saline, balanced salt solution, or glycine (i.e., amino acid)-HCl solution neutralized with sodium carbonate (see pages 27 and 34; and Example 7).

Although Kappler *et al.* do not expressly recite the functional properties of their modified SEBs, such as, inhibitory activity on T cell activation; interaction with specific Vβ component of T cell receptor; and reduced immunological responsiveness, these functional limitations represent the inherent properties of Kappler 's modified SEBs. Because of the identical structure and the identical bacterial origin of the prior art prophylactic or therapeutic modified SEBs, the prior art modified SEBs are viewed as the same as the modified SEBs or derivatives thereof claimed in the instant claims, and therefore these modified SEBs are expected to have the same intrinsic functional properties as that of the Applicants' modified SEBs or derivatives thereof. The Office's position that the prior art modified SEBs are the same as Applicants' modified SEBs or derivatives thereof is based upon the fact that every structural characteristic overlapping in the prior art modified SEBs and the Applicants' disclosure are the same. In spite of the fact that the prior art is silent about the disclosed functional characteristics of the Applicants' modified SEBs or derivatives thereof, there is sufficient overlap to reasonably conclude that the prior art modified SEBs thereof are one and the same as the Applicants' SEBs or derivatives thereof. Since the prior art modified SEBs are structurally the same as the SEBs or derivatives thereof claimed in the instant claims, the prior art SEBs are expected to have the prophylactic capacities or inhibitory properties as recited in the instant claims. The functional properties are viewed as intrinsic functions inseparable from the modified SEBs of the prior art. See *Northam Warren Corp. v. D. F. Newfield Co., 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934)* (A patent to a pencil for cleaning fingernails was held invalid because a pencil of the same structure for writing was found in the prior art.). In the instant application, Kappler's product or composition is viewed as inherently having the prophylactic capacities or inhibitory properties as recited in the instant claims.

The limitations 'for immunopathy' or 'for oral administration' are not required structural

elements of the product or composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)*. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)*. Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best, 562 F.2d at 1255, 195 USPQ at 433*.

Claims 1, 3, 5 and 9-13 are anticipated by Kappler *et al.*

Objection(s)

33) Claim 1 is objected to for lacking a period at the end of the claim.

Remarks

34) Claims 1, 3, 5 and 9-13 stand rejected.

35) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

36) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission

of after-final amendments is (703) 872-9307.

37) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

38) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

July, 2004

S. DEVI, PH.D.
PRIMARY EXAMINER